TEMPORARY ARTERIAL SHUNT AND METHOD

Field of the Invention:

[0001] This invention relates to temporary conduits for use in vascular surgical procedures, and more particularly to a temporary shunt for easy insertion into, and removal from, a target vessel in a living body.

Background of the Invention:

[0002] During arterial reconstruction or bypass procedures, the target artery is generally clamped proximal and distal to an anastomotic site for a brief interval to provide a blood-free field for performing the anastomosis. However, interruption of blood flow in the recipient artery may be dangerous to the patient. Ischemia to the heart during coronary artery bypass may result in myocardial infarction. Similarly, ischemia to the brain during carotid endarterectomy may result in stroke. Consequently, surgeons often place an arterial shunt in the artery undergoing reconstruction, to avoid the potential for ischemic complications. The arterial shunt is a flexible tube that is inserted into the arteriotomy. The outer diameter of the shunt approximates the inner diameter of the artery, so

that flow is maintained in the artery and ischemia does not occur as the arterial bypass or endarterectomy is being performed.

[0003] Presently, it is difficult to remove a shunt following its use. As the anastomosis is being completed, or the artery is being closed following endarterectomy, the last several suture loops at the entry site of the shunt are not cinched down, and the shunt is worked out of the artery. Shunt removal is a delicate process, and it may be difficult to perform without disrupting the anastomosis being formed. The anastomotic suture may be broken, or tension on the suture may cause it to cut through the arterial wall.

Summary of the Invention:

[0004] In accordance with an embodiment of the present invention, a shunt is formed of a coiled strand, with a loop of the strand extending out of the center of the formed shunt. A tube is positioned over the center loop against the shunt to aid in removing the shunt by uncoiling the coiled strand for retrieval through the tube. The distal ends of the shunt may contain bulbous portions formed out of the strand to enhance fluid-tight sealing of the shunt within the inner walls. Alternatively, the coiled strand may form a tapered shunt, with one end of greater diameter than the other end.

[0005] In use, the shunt is placed into an incision in a vessel, with one end of the shunt contacting the inner wall of the vessel proximal to the incision and the other end of the shunt contacting the inner wall of the vessel distal to the incision. The anastomosis is sewn with only the loop extending out of the anastomotic attachment. A stitch is placed on either side of the loop as it exits the intra-vessel portion of the shunt. At the completion of the anastomosis, before the ends of the suture are tied, the removal tube is brought down to the vessel surface, and held stationary with a pair of curved or right-angled clamps. The loop of the shunt is pulled against the tube to cause the shunt to dissemble and peel away into a strand for removal through the tube. The stationary tube rests against the outer surface of the shunt during the dissembly process to assure that the suture line is not stressed as tensile force is exerted on the loop to unravel and remove the shunt. In this way, substantially all the force required to disassemble the shunt is exerted against the distal end of the tube.

<u>Brief Description of the Drawings</u>:

[0006] Figure 1 is a perspective view of a flexible tensile element such as a suture coated with a thermoplastic polymer;

[0007] Figure 2 is a perspective view of the tensile element of Figure 1 being formed around a mandrel;

[0008] Figures 3 is a perspective view of the tensile element coiled about the mandrel;

[0009] Figure 4 is a perspective view of the shunt formed from the fused tensile element;

[0010] Figure 5 is a perspective view of the dissembled shunt as retrieved through a removal tube;

[0011] Figures 6a-6c are partial plan views of a mandrel for forming bulbous ends on a shunt in accordance with an embodiment of the present invention;

[0012] Figure 7 is a flow chart illustrating the process of installing and removing a temporary shunt in accordance with an embodiment of the present invention; and

[0013] Figure 8 is a sectional view of the shunt being inserted into an artery.

<u>Detailed Description of the Invention</u>:

[0014] Referring now to Figures 1 and 2, there is shown an embodiment of the present invention in which a tubular member for use as

an arterial shunt is formed as a coil including a plurality of substantially contiguous convolutes of an elongated strand that may be coated with a bioinert and preferably thermoplastic polymer. The strand 9 is wound on a mandrel 17 that has a substantially constant diameter between the ends thereof, with a protruding loop 13 formed intermediate the ends. The strand is constructed from a length of suture or wire that is coated with a material such as polyvinyl chloride, polyurethane, silicone rubber, or the like. The center of the length of strand is formed into the loop 13 of length approximately 5cm. The two strands at the bottom of the loop 13 may be held together by a tie 15 such as a band heat-sealed to the strands, or by a length of heat shrink tubing, or by a suture winding, or held together by adhesive, or by welding a length of adjacent strands together using heat or solvent bonding, or the like.

[0015] The strand 9 with its formed center loop 13 is continuously wound around a rod-like mandrel 17, as shown in Figures 2 and 3, with adjacent convolutes of the coil substantially in contact with one another. The ends of the strand 9 are temporarily held onto the mandrel 17 using clips, clamps, elastic bands, sutures, or the like, as shown in Figure 3. The adjacent convolutes of the continuously coiled and looped strand 9 are then bonded together by heating and pressing the thermoplastic coating, or by

adhesive bonding or solvent bonding or by surface coating, or the like, to form the tubular, liquid-impervious conduit 19 that serves as the arterial shunt, as shown in Figure 4. Expanded bulbous ends may be formed on the distal ends of the shunt by expanding a corresponding portion of the mandrel 17, as shown in Figures 6a-6c, prior to winding and bonding of the coiled and looped strand. The ends of the mandrel 17 may then be contracted to allow release of the bonded shunt 19.

[0016] The shunt 19 may also be formed with varying pitch of adjacent convolutes along the tubular length thereof to promote varied flexibility between the ends. As shown, for example, in Figure 8, greater bending occurs near the center and ends as the shunt 19 is inserted into the artery 29. Also, the shunt 19 may be formed of the strand wound in opposite directions between the protrusion and each end, or may be formed with tapering cross section between the ends, for example, to establish a selected pressure drop through the shunt where desirable in certain surgical environments. Additionally, shunt 19 may be formed of a strand 9 that is disposed, for example, along a serpentine pattern from end to end, or from center to each end, about the entire periphery of the tubular shunt 19. Also, the loop 15 may be disposed closer to one of the spaced ends to facilitate earlier insertion of the shunt into an artery. In another embodiment, the ends

of the strand 9 may be routed through the tubular conduit from the spaced ends to be brought out through a central portion of the tubular member as the protrusion on which tensile force is exerted in order to dissemble the shunt inwardly from the spaced ends toward the center.

[0017] In each such form of the shunt 19, the region between adjacent convolutes or wraps of the strand constitutes a continuous region of diminished tensile and shear strength whether formed by heating and pressing together of a thermoplastic surface layer, or by surface coating, or by adhesive or welded attachment of the adjacent convolutes in order to assure that disassembly of the tubular shunt occurs along such region, as later described herein.

[0018] Referring now to the partial plan views of Figures 6a-6c, the expandable end portions of the mandrel 17 may be constructed as lengths of longitudinally split tube 23 with an internally threaded portion 21 proximal to the split portions 23. Bolts 25 threaded into the ends of the mandrel 17 compress the split portions 23 of the mandrel and cause them to expand. Formation of the mandrel from resilient material allows the mandrel 17 to contract to its natural, undilated position. Upon removal of the threaded bolts 25, the associated tubular conduit 19 thus formed around such expandable mandrel 17 includes bulbous extreme ends that promote

superior liquid sealing against the arterial walls when positioned within the target artery. A removal tube 31 may be captivated overlaying the loop 13 by attaching a ring 33 through the loop 13 of the larger diameter than can pass through the removal tube 31.

[0019] In operation, and with reference to the flow chart of Figure 7 and the sectional view of Figure 8, the tubular conduit 9 is sufficiently flexible and resilient when formed as previously described to facilitate reasonably easy insertion 36 of the ends through an aperture 27 in a vessel wall 29. Then, by manipulating extension of the remote ends of the tubular conduit 19 into upstream and downstream positions 30, 32 relative to the vascular aperture 27, the tubular conduit 19 can be so positioned 38 to serve as a vascular shunt through the region of the aperture 27 to promote continued blood flow during vascular surgery 40 through the inside of the convolutes for the reconstruction or formation of a vascular bypass on the target vessel 29 proceeds. The integral loop 13 remains protruding through the vascular aperture 27 and through a partially completed anastomosis 42 (not shown) to facilitate later removal of the shunt 19 from within the vessel 29.

[0020] In an arterial bypass anastomosis or arterial reconstruction, and before first and last stitches of the suture are tied off, the central loop 13

remains protruding through the incomplete segment of the anastomosis to facilitate convenient removal of the shunt with minimal disturbance of surrounding tissue. Specifically, a removal tube 31, as shown in Figures 4 and 8, is positioned 44 over the central loop 13 against the shunt 19, with the distal end of the removal tube 31 disposed between first and last stitches in the incomplete segment of the anastomosis. The loop 13 is then tensioned 46 relative to the removal tube 31, which can be retained in fixed position relative to the artery 29, in order to unravel the shunt 19 for removal 48 from within the artery through the removal tube 31 as the looped, continuous strand 9, as shown in Figure 5. Removal of the strand 9 and associated liquid-impervious layer thereon through the removal tube 31 in this manner thus minimizes dissociative forces applied to the target artery 29 or the anastomosis which can then be completed 50 by tightening the sutures and tying off the ends, with resultant minimum loss of blood or interruption of arterial blood flow.

[0021] Therefore, the method and apparatus of the present invention provide a temporary shunt to facilitate blood flow through a target vessel during vascular reconstruction or bypass surgery. Various configurations of the tubular conduit facilitate insertion and removal of the shunt with minimum blood loss or interruption of blood flow.